UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

DEFENDANTS' REPLY IN SUPPORT OF THEIR JOINT MOTION TO EXCLUDE THE OPINIONS OF DAVID MADIGAN, PH.D.

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Plaintiffs begin their Brief in Opposition to Defendants' Motion to Exclude the General Causation Testimony of Plaintiffs' Expert David Madigan, Ph.D. (the "Opposition" or "Opp.") with a telling admission that "Dr. Madigan is not giving a general causation opinion in this case." Opp. at 3. Plaintiffs instead assert that Dr. Madigan's opinions "provide additional support and insight into the studies that underl[ie] the general causation opinions of Plaintiffs' experts." Opp. at 4. That premise, however, is unsupportable; none of Plaintiffs' other experts cite to or rely upon Dr. Madigan's analysis in any way. Because they purport to be able to offer their opinions without reference to Dr. Madigan's statistical "support," it necessarily follows that the support is not informative on the issue and is irrelevant.

Plaintiffs also stress that "[Dr. Madigan] is providing statistics based expert testimony." Opp. at 3. But statistics in a vacuum are meaningless; to be relevant here, the statistical analysis must address the general causation inquiry. Yet Dr. Madigan expressly disclaims that, and for good reason. He is not qualified to opine on whether exposures to NDMA and/or NDEA causes cancer, because he is not a medical doctor, epidemiologist, or toxicologist and does not have the training and experience needed to offer such testimony. Moreover, because no expert who claims to be qualified to speak to the general causation inquiry cites to, relies upon, or was informed by Dr. Madigan's statistical analysis, his "statistics based expert testimony" has no meaningful application to general causation.

Finally, even if Dr. Madigan were qualified to opine on general causation and/or his opinions were materially relevant to some expert who actually addressed the question at hand, they still should be excluded. Dr. Madigan's opinions are based on flawed and unreliable methodology. He has not considered key epidemiological evidence and has misrepresented other evidence. He also has not assessed and has no basis to offer any opinions on whether NDEA causes any cancer, or whether NDMA causes several of the cancers claimed by Plaintiffs to be at issue in this litigation. Accordingly, Dr. Madigan's opinions should be excluded.

ARGUMENT

I. DR. MADIGAN'S OPINIONS SHOULD BE EXCLUDED BECAUSE THEY ARE NOT GENERAL CAUSATION OPINIONS AND NO OTHER EXPERT RELIES UPON OR WAS INFORMED BY THEM.

Plaintiffs concede that "Dr. Madigan is not giving a general causation opinion in this case." Opp. at 3. That concession alone warrants granting Defendants' Motion. The only question at issue in this stage is general causation. Plaintiffs concede Dr. Madigan's opinions do not answer that question. The Court thus need not go any further in assessing the admissibility of his testimony and opinions.[1]

[1] Surprisingly, after conceding that Dr. Madigan is not offering any general causation opinions, Plaintiffs argue that Dr. Madigan is offering a "partial general causation opinion." Opp. at 4. Plaintiffs claim to cite case law that "demonstrates an expert is permitted to provide opinions that underl[ie] general causation **but are not general causation opinions themselves**." *Id*. Of course, Plaintiffs' citation only confirms their concession that Dr. Madigan **is not offering general causation opinions**—whole or partial—which are the only relevant opinions here.

In their Opposition, Plaintiffs repeatedly claim that Dr. Madigan is providing statistics-based expert testimony to "provide additional support and insight into the studies that underl[ie] the general causation opinions of Plaintiffs' experts." In fact, none of the four other experts proffered by Plaintiffs cites to or relies upon Dr. Madigan's analysis in any way. Dr. Hecht conceded he is not relying upon Dr. Madigan's analysis. Hecht Dep., Dkt. 1714-16, at 270:6-9 ("Q: And I take it that you're not relying upon any other expert retained by plaintiff to support any of your opinions in this case? A: Correct."). Dr. Panigrahy also conceded he is not relying upon Dr. Madigan's analysis. Panigrahy Dep., Dkt. 1716-4, at 41:14-19. Dr. Lagana conceded he has never read Dr. Madigan's report. Lagana Dep., Dkt. 1718-5, at 25:13-14. Dr. Etminan conceded he has never spoken to Dr. Madigan and does not cite Dr. Madigan's analysis. Etminan Dep., Dkt. 1717-4, at 13:1-3; *see also* Etminan Rep., Dkt. 1717-3, at 35-40.

Disregarding their own experts' admissions, Plaintiffs claim Dr. Madigan's testimony is admissible because an expert's opinion is not "excludable because it provides testimony regarding only one facet or aspect of an action but does not prove the whole case" or underlies general causation but is not itself a general causation opinion. Opp. at 4 (citing *Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Litig.*, 509 F. Supp. 3d 116, 131 (D.N.J. 2020)). But Dr. Madigan's testimony involves no facet or aspect of general causation. His opinions

are no more than an amalgamation of statistical calculations that Dr. Madigan performed on inapposite dietary studies, without any interpretation or causal reasoning—which Plaintiffs concede Dr. Madigan does not give and which other courts previously have ruled he would be unqualified to give. They cannot "underlie" any expert's general causation opinion because no expert who opines on general causation considered them, rendering *Johnson and Johnson* inapposite.

Dr. Madigan's opinions also do not fit the circumstances in which an expert provides only a partial answer on causation. *See, e.g.*, *Feit v. Great-West Life & Annuity Ins. Co.*, 460 F. Supp. 2d 632, 641-42 (D.N.J. 2006). Dr. Madigan expressly disclaims any general causation opinion at all. His report contains no analysis that even purports to answer a causation question or any part thereof. Further, even testimony that is material to an ultimate question must be based on reliable methodology and must reliably flow from that methodology and the facts. *See id.* at 641. Dr. Madigan's testimony and opinions fail both these tests.

II. PLAINTIFFS FAIL TO DEMONSTRATE DR. MADIGAN'S QUALIFICATIONS TO RENDER GENERAL CAUSATION OPINIONS IN THIS CASE.

Plaintiffs cannot dispute that multiple Courts have previously found Dr. Madigan is not qualified to opine on general causation. In their Opposition, Plaintiffs attempt to avoid these findings by contending that the two cases cited by Defendants are not applicable. Opp. at 4. Plaintiffs falsely claim that Dr. Madigan was excluded

in those prior cases for failing to conduct a meta-analysis or independent research. They argue that "[m]eta-analyses were conducted by Dr. Madigan in this case unlike in *In re Accutane Litig.* and independent research was completed by Dr. Madigan in this case, unlike in *In re Incretin-Based Therapies Prod. Liab. Litig*." Opp. at p. 11. That was not the issue. Instead, the courts in *Accutane* and *Incretin* correctly concluded that Dr. Madigan's qualifications as a statistician do not qualify him to apply statistics to medical and scientific questions beyond his expertise.

Moreover, Plaintiffs do not even attempt to address Dr. Madigan's exclusion from offering any medical or scientific opinions in *In re Abilify (Aripiprazole) Products Liability Litigation,* where he admitted his lack of expertise. Opp. at 4. Nor do Plaintiffs dispute that Dr. Madigan was disallowed from offering certain opinions in *In re Vioxx Products Liability Litigation* because the Court found that such testimony would be outside of his field of expertise. Opp. at 5.

Instead, Plaintiffs argue that the *Abilify* and *Vioxx* courts both permitted Dr. Madigan's statistical analysis of the underlying data to provide additional context and insight into the underlying basis for general causation. Opp. at 6. Plaintiffs omit that, in *Vioxx*, one of the plaintiff's experts testified that he intended to rely on Dr. Madigan's statistical analysis. *See In re Vioxx Prod. Liab. Litig.*, MDL 1657, 2016 WL 8711273, at *3 (E.D. La. Sept. 16, 2016) ("[Defendant] argues that the Court should exclude the expert opinions of Dr. Madigan concerning…[a] statistical

analysis that a different [p]laintiff's expert, Dr. Egilman, has testified that he intends to rely on."). Plaintiffs and Dr. Madigan cannot have it both ways: they cannot disclaim he is offering general causation opinions to avoid the fact that courts have previously ruled he is unqualified to do so, then claim that his opinions "support" general causation analyses, when no other expert actually relies on them.

Plaintiffs similarly argue other courts have permitted Dr. Madigan to offer statistical analysis of underlying data. Here, however, Dr. Madigan purports to calculate cumulative NDMA exposures from inapposite dietary studies and then, without analytical support or medical qualifications, offers the quasi-medical conclusion: "it is scientifically plausible that users of contaminated valsartan could develop cancer." Madigan Rep., Dkt. 1715-4, ¶¶ 33-35. Courts have expressly prohibited Dr. Madigan from applying statistical analysis to draw causation conclusions. Here, Dr. Madigan's report offers a "scientific plausibility" conclusion he is not qualified to offer and which does not flow from his reporting of supposed increased cancer risk in consumers of dietary nitrosamines. Those conclusions are indistinguishable from the general causation opinions Dr. Madigan has previously been excluded from offering, and Defendants respectfully submit they should be excluded again here.

III. DR. MADIGAN'S METHODOLOGY IS FLAWED AND UNRELIABLE.

A. Dr. Madigan's Reliance on Dr. Etminan's Literature Search is Fundamentally Flawed.

An expert may rely on another expert only when the expert independently assesses the reliability of the other expert's opinions; blind reliance on the other expert is impermissible. *See Snodgrass v. Ford Motor Co.*, 2002 WL 485688, at *40 (D.N.J. Mar. 28, 2002) (excluding an opinion of plaintiff's statistician due to his blind reliance on data compiled and provided by plaintiff's counsel); *see also In re TMI Litig.*, 193 F.3d 613, 716 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000) (upholding exclusion of an expert who failed to assess the validity of opinions of the experts relied upon). Dr. Madigan's opinions are based on a subset of medical literature selected by Dr. Etminan, another plaintiffs' expert. Plaintiffs respond with a blanket assertion that Dr. Madigan "searched for other relevant materials and reviewed additional literature to ensure that Dr. Etminan had not missed anything." Opp. at 8. That is simply false. Dr. Madigan conducted no independent searches of any literature database; he testified only that he reviewed the citing references within the papers selected by Dr. Etminan and looked for an update to one metanalysis. *See* Mot. at 15-16. That is not an independent search. Dr. Madigan's blind reliance on Dr. Etminan renders his opinions unreliable.

Further, Plaintiffs have not come forward with any objective, verifiable

evidence that Dr. Madigan's testimony is based on scientifically valid principles, as required by law. *See In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 670 (D.N.J. 2008) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (when proposed expert testimony is not based upon independent research, but instead on a literature review, the party proffering such testimony must present evidence the testimony is based on scientifically valid principles)).

Plaintiffs claim Dr. Madigan was retained to analyze the underlying data in epidemiological studies. Opp. at 1. If so, Dr. Madigan did not do what he was retained to do, as he did not "analyze" any underlying, raw study data. In fact, Dr. Madigan admitted that he did not have any underlying data. (Madigan Dep., Dkt. 1715-5, at 112:6-13 ("Q: So[,] my question is, did you look at each of the papers and do an assessment to determine if the dose response was in fact linear? A: So[,] I don't have access to the data, the raw data, so I'm relying on the analysis that the authors did."). Dr. Madigan analyzed reported results from the studies Dr. Etminan selected, without looking to see whether there was other relevant data and without the underlying raw data. Critically, Dr. Magian's purported analysis of data is not meaningful without a cancer causation expert to opine on what those statistics mean. None of Plaintiffs' experts offer such an opinion, and Dr. Madigan is not qualified to do so.

B. Dr. Madigan's Testimony is Not Reliable.

Dr. Madigan plainly does not have the medical background or qualifications to offer the conclusion set forth in his report — *i.e.*, "…it is scientifically plausible that users of contaminated valsartan **could develop** cancer" — and he does not even attempt to support that statement. Plaintiffs' assertion that the words "scientifically plausible" are merely a descriptor for his statistical conclusions is unavailing. The phrase is a thinly-veiled attempt to offer the ultimate general causation opinion Dr. Madigan has disclaimed. If statistics, standing alone, were capable of supporting a general causation opinion Dr. Madigan would not have disclaimed one, nor would the record be replete with examples of his exclusion from offering similar opinions.

Dr. Madigan's final conclusion also belies Plaintiffs' assertion that his opinions provide support for general causation opinions. Dr. Madigan, by his own admission, has no basis to opine on cause. According to Plaintiffs, Dr. Madigan is not offering general causation opinions, he is only offering "statistical support." Therefore, he should not be allowed to render the conclusion.

Plaintiffs' Opposition also misrepresents the studies Dr. Madigan purportedly conducted. Plaintiffs assert that Dr. Madigan calculated the mean "lifetime cumulative exposure" to NDMA and NDEA in each study to enable comparison of the studies to Plaintiffs. Opp. at 1-2. That is false. The studies on which Dr. Madigan relies focus primarily on dietary exposure to NDMA as *estimated* from notoriously

unreliable food frequency questionnaires. Using that unreliable metric, Dr. Madigan then leaps from estimated dietary exposure data to an unsupportable conclusion about lifetime cumulative exposure (assuming diet is static and neglecting non-dietary sources of NDMA) to a conclusion about the "scientific plausibility" of Plaintiffs developing cancer from taking valsartan. Dr. Madigan's testimony is layered with unfounded inferential leaps. *See* Mot. at 22-26.

Dr. Madigan has no information about Plaintiffs' actual exposure. Instead, he assumes the highest possible exposure as measured in valsartan and that such exposure occurred every day, which is virtually impossible. Even FDA has stated that it is highly improbable anyone was exposed at such a level.[2]

Dr. Madigan also blindly relies on Dr. Panigrahy's opinion that inhaled NDMA is toxicologically equivalent to orally consumed NDMA. Plaintiffs admit that "Dr. Madigan defer[ed] to Dr. Panigrahy's exposure assessment (rather than conducting such an assessment himself) in order to translate the amount of inhaled NDMA into the equivalent amount of orally ingested NDMA." Opp. at 14.

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[2] *See* Scott Gottlieb, M.D., *FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues*, U.S. Food & Drug Administration Press Announcements (January 25, 2019), https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps; *Statement on the Agency's ongoing efforts to resolve safety issue with ARB medications*, U.S. Food & Drug Administration Press Announcements (August 28, 2019), https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications).

According to Plaintiffs, "Dr. Madigan is permitted to rely on [Dr. Panigrahy's] expert opinion in the field of medicine when forming his own opinion in the field of biostatistics." Opp. at 15. Plaintiffs attempt to couch Dr. Madigan's flawed methodology as deference, but it is really blind reliance. Dr. Madigan did nothing to assess whether Dr. Panigrahy's opinion was reliable. In turn, Dr. Panigrahy did not provide any basis for his exposure assessment opinion. Instead, he just told Dr. Madigan that it was accurate; and, because Dr. Madigan blindly relied on it, he did not discover that it had no support. Of course, contrasting inhalation and oral exposures to NDMA is not medicine; it is toxicology, in which Dr. Panigrahy admits having no expertise or formal training. (Panigrahy Dep., Dkt. 1716-4,119:4-11). Dr. Madigan's blind reliance on Dr. Panigrahy's unreliable and unsupported assertions also renders Dr. Madigan's opinions unreliable. As such, they should be excluded.

C. Dr. Madigan Ignored Key Epidemiology Literature that Contradicts His Opinions.

Plaintiffs concede that the collection of literature Dr. Madigan reviewed did not include the human epidemiology studies of valsartan. Opp. at 1. Specifically, Plaintiffs acknowledge, "[t]he collection of literature Dr. Madigan reviewed included [only] human dietary and occupational exposure studies which quantified NDMA and/or NDEA exposure." Opp. at 1. Plaintiffs go on to assert that "it is scientifically impracticable for Pottegard to be analyzed against the other studies Dr. Madigan considered as it lacked an essential requirement: quantifying the amount of

NDMA." Opp. at 12. This misrepresents the Pottegard study, which analyzed users of valsartan and found no statistically significant increased risk of cancer among those exposed to the NDMA impurity. Unlike the inapposite dietary studies Dr. Madigan preferred, users of valsartan containing the NDMA impurity are directly analogous to Plaintiffs. Dr. Madigan's deliberate neglect of this critical data reveals his opinions for what they are: conclusion-driven advocacy without scientific rigor.[3]

Similarly, Plaintiffs misstate that Dr. Madigan "provided a viable and reasonable explanation, based in biostatistical fundamentals, for excluding [] Gomm." Opp. at 13. Dr. Madigan testified that he ignored Gomm because he does not read German. Madigan Dep. at 282:25-283:9. Plaintiffs ignore that testimony and point to the same weak rationale recycled from Dr. Madigan's failure to consider Pottegard. The Gomm study — available online in English — contains the most on-point data available. After assessing more than 800,000 users of valsartan, the authors did not find any statistically significant increased risk of cancer among those exposed to NDMA, outside a nominally significant increased risk of liver cancer. Dr. Madigan's weak arguments about quantifying NDMA are unpersuasive. He deliberately neglected data that did not fit his conclusion-driven approach.

[3] Plaintiffs also apparently overlook the inherent problem with their argument: any difficulty in calculating the levels of exposure to NDMA among the Pottegard subjects (who consumed valsartan containing NDMA), applies equally to Plaintiffs' NDMA exposure. Plaintiffs' current motion to certify a medical monitoring class action claims precisely the opposite.

Indeed, that very conclusion-drive approach is why Dr. Madigan's opinions were excluded in *Accutane*. There, the court viewed Dr. Madigan's refusal to perform meta-analysis and his reliance instead on one study to the exclusion of others as "an attempt to explain away the body of evidence on causation[.]" *In re Accutane Litigation*, 234 N.J. 340, 373 (2018). Dr. Madigan does the same here: he cherry-picks evidence supportive of his opinions and ignores the rest.

Plaintiffs try to explain away the *Accutane* ruling by asserting, wrongly, that Dr. Madigan was "largely" disqualified due to "underlying issues" that were present in *Accutane* but "are not at all present here." Opp. at 9-10. Specifically, Plaintiffs argue that Dr. Madigan's opinions were disqualified due to his failure to complete a meta-analysis of the risk assessment studies. Opp. at 9. But a metanalysis of the sources selected for Dr. Madigan by Dr. Etminan does not obviate the same litigation-driven problem. Leaving aside that Dr. Madigan's cited metanalysis is of dietary nitrosamine studies — tangentially relevant, at best — it does not address his failure to consider the directly analogous human valsartan studies. Just as in *Accutane*, he was willfully blind to critical data that did not fit with the conclusion he was hired to deliver. His feeble attempts to explain that flawed methodology fail.

IV. DR. MADIGAN'S OPINIONS REGARDING NDEA AND CANCER SHOULD BE EXCLUDED, AND DR. MADIGAN HAS DISCLOSED NO ANALYSIS OF SEVERAL CANCERS.

Plaintiffs assert that "Dr. Madigan analyzed the Zheng study and the data therein that showed a possible relation between NDEA and pancreatic cancer because it was the only study that quantified the amount of NDEA." Opp. at 25. The Zheng study does not provide sufficient basis for any of Dr. Madigan's opinions regarding NDEA and cancer and provides no basis for opinions about any cancer other than pancreatic cancer. Indeed, as the study authors state "these findings need to be confirmed in readily available large, prospective cohort studies…" Plaintiffs do not offer any argument that these findings are sufficient, conceding they show only "a possible relation between NDEA and pancreatic cancer" and cannot point to a single evidentiary link between NDEA and any other cancer. (Zheng, et al.). Dr. Madigan has zero basis to offer any opinions on NDEA.

Plaintiffs make a blanket statement that "Dr. Madigan did his due diligence as a biostatistician by examining the forty-three NDEA related references in Zheng." Opp. at 25. Plaintiffs do not argue (because they cannot) that any such reference supports a link between NDEA and causation of cancer. Plaintiffs assert that, "[a]t most, this is a case specific issue to be addressed with individual plaintiffs." Opp. at 26. Not so. The only issue before the Court at this stage is general causation. Plaintiffs tacitly concede that Dr. Madigan cannot address that question as to NDEA. As such, any opinions concerning NDEA must be excluded.

Plaintiff's Opposition also does not address or dispute that Dr. Madigan has not assessed and has no basis to offer any opinions on cancers of the bladder, breast, blood, kidney, pharynges, prostate, or uterus, all of which are purportedly at issue in this litigation. Accordingly, at a minimum, Dr. Madigan should be precluded from offering any opinions or testimony about those cancers.

CONCLUSION

Plaintiffs concede that Dr. Madigan is not giving a general causation opinion in this case and, as other courts have ruled, he is not qualified to do so. As such, his opinions cannot stand on their own to answer the general causation inquiry. Because no qualified expert cited to or relied upon his analyses, his opinions do not provide "support" for or a "partial" answer to that inquiry. Dr. Madigan also failed to use a sufficiently reliable methodology. He started with a subset of literature selected by another expert without conducting independent searches. He then knowingly excluded relevant epidemiological literature. He parroted the opinions of another one of Plaintiffs' experts without assessing their reliability. Finally, Dr. Madigan has offered no basis for offering any opinions or testimony about NDEA. Nor has he offered any basis for offering any opinions or testimony on bladder, breast, blood, kidney, pharyngeal, and uterine cancers. For those, Defendants respectfully request that the Court exclude or, at minimum, limit Dr. Madigan's opinions.

Dated: January 6, 2022

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 6, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Seth A. Goldberg
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